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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
09/724,000	11/28/00	POLVERINO	A	MBHB00-450-A

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EXAMINER	
RAWLINGS, S	
ART UNIT	**PAPER NUMBER**
1642	7

DATE MAILED: 04/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/724,000	POLVERINO ET AL.	
	Examiner	Art Unit	
	Stephen L. Rawlings, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-56* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☒ Other: *Restriction Election facsimile sheet* .

DETAILED ACTION

1. Claims 1-56 are pending in the application and are currently subject to restriction.

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Elections/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

Group 1. Claims 1-8, 10, 11, and 43-45, in so far as the claims are drawn to an isolated nucleic acid molecule comprising the polynucleotide sequence set forth in SEQ ID NO: 1 encoding a polypeptide with the amino acid sequence set forth in SEQ ID NO: 2, a vector comprising said nucleic acid molecule, a host cell comprising said vector, a process of producing said polypeptide, and a composition comprising said nucleic acid molecule, classified in class 536, subclass 23.5, class 435, subclass 320.1, and class 435, subclass 325.

Group 2. Claims 1-8, 10, 11, and 43-45, in so far as the claims are drawn to an isolated nucleic acid molecule comprising the polynucleotide sequence set forth in SEQ ID NO: 4 encoding a polypeptide with the amino acid sequence set forth in SEQ ID NO: 5, a vector comprising said nucleic acid molecule, a host cell comprising said vector, a process of producing said

polypeptide, and a composition comprising said nucleic acid molecule, classified in class 536, subclass 23.5, class 435, subclass 320.1, and class 435, subclass 325.

Group 3. Claims 9, 13-17, 37-42, 46, and 47, in so far as the claims are drawn to an isolated polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 2 or a derivative thereof, a composition comprising said polypeptide, and a fusion protein comprising said polypeptide, classified in class 530, subclass 350, class 530, subclass 402, and/or class 435, subclass 183.

Group 4. Claims 9, 13-17, 37-42, 46, and 47, in so far as the claims are drawn to an isolated polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 5 or a derivative thereof, a composition comprising said polypeptide, and a fusion protein comprising said polypeptide, classified in class 530, subclass 350, class 530, subclass 402, and/or class 435, subclass 183.

Group 5. Claims 12, 52, and 53, in so far as the claims are drawn to a process for determining whether a compound binds to the polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 2 and/or inhibits the activity of said polypeptide, classified in class 435, subclass 7.1.

Group 6. Claims 12, 52, and 53, in so far as the claims are drawn to a process for determining whether a compound binds to the polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 5 and/or inhibits the activity of said polypeptide, classified in class 435, subclass 7.1.

Group 7. Claims 18-32, 34, and 35, in so far as the claims are drawn to an antibody produced by immunizing an animal with a peptide comprising an amino acid sequence of SEQ ID NO: 2 or a fragment or derivative thereof and a hybridoma producing said antibody or fragment thereof, classified in

class 530, subclass 387.1 and/or subclass 388.1 and class 435, subclass 326.

Group 8. Claims 18-32, 34, and 35, in so far as the claims are drawn to an antibody produced by immunizing an animal with a peptide comprising an amino acid sequence of SEQ ID NO: 5 or a fragment or derivative thereof and a hybridoma producing said antibody or fragment thereof, classified in class 530, subclass 387.1 and/or subclass 388.1 and class 435, subclass 326.

Group 9. Claim 36, in so far as the claims are drawn to a method for detecting or quantifying a polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 2, classified in class 435, subclass 7.1.

Group 10. Claim 36, in so far as the claims are drawn to a method for detecting or quantifying a polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 5, classified in class 435, subclass 7.1.

Group 11. Claims 33, in so far as the claims are drawn to a method for treating, preventing, or ameliorating a disease associated with the protein comprising the amino acid sequence set forth in SEQ ID NO: 2, classified in class 424, subclass 130.1.

Group 12. Claims 33, in so far as the claims are drawn to a method for treating, preventing, or ameliorating a disease associated with the protein having the amino acid sequence set forth in SEQ ID NO: 5, classified in class 424, subclass 130.1.

Group 13. Claims 48 and 49, in so far as the claims are drawn to a method for treating, preventing, or ameliorating a medical condition comprising administering the protein having the amino acid sequence set forth in SEQ ID NO: 2, classified in class 424, subclass 184.1.

Group 14. Claims 48 and 49, in so far as the claims are drawn to a method for treating, preventing, or ameliorating a medical condition comprising administering the protein having the amino acid sequence set forth in SEQ ID NO: 5, classified in class 424, subclass 184.1.

Group 15. Claim 50, in so far as the claims are drawn to a method for diagnosing a pathological condition or a susceptibility to said condition comprising determining the presence or amount of the polypeptide having the amino acid sequence set forth in SEQ ID NO: 2, classified in class 435, subclass 7.1.

Group 16. Claim 50, in so far as the claims are drawn to a method for diagnosing a pathological condition or a susceptibility to said condition comprising determining the presence or amount of the polypeptide having the amino acid sequence set forth in SEQ ID NO: 5, classified in class 435, subclass 7.1.

Group 17. Claim 51, in so far as the claims are drawn to a device comprising cells that secrete a protein polypeptide having the amino acid sequence set forth in SEQ ID NO: 2, classified in class 424, subclass 277.1.

Group 18. Claim 51, in so far as the claims are drawn to a device comprising cells that secrete a protein polypeptide having the amino acid sequence set forth in SEQ ID NO: 5, classified in class 424, subclass 277.1.

Group 19. Claim 54, in so far as the claims are drawn to a method for modulating the levels of a protein comprising administering to an animal the nucleic acid encoding said protein, which has the amino acid sequence set forth in SEQ ID NO: 2, classified in class 514, subclass 44.

Group 20. Claim 54, in so far as the claims are drawn to a method for modulating the levels of a protein comprising administering to an animal the nucleic acid encoding said protein, which has the amino acid sequence set forth in SEQ ID NO: 5, classified in class 514, subclass 44.

Group 21. Claim 55, in so far as the claims are drawn to a transgenic mammal comprising the nucleic acid molecule comprising the polynucleotide sequence set forth in SEQ ID NO: 1, classified in class 800, subclass 13.

Group 22. Claim 55, in so far as the claims are drawn to a transgenic mammal comprising the nucleic acid molecule comprising the polynucleotide sequence set forth in SEQ ID NO: 5, classified in class 800, subclass 13.

Group 23. Claim 56, in so far as the claims are drawn to a process for using a transgenic mammal comprising the nucleic acid molecule comprising the polynucleotide sequence set forth in SEQ ID NO: 2, classified in class 800, subclass 3.

Group 24. Claim 56, in so far as the claims are drawn to a process for using a transgenic mammal comprising the nucleic acid molecule comprising the polynucleotide sequence set forth in SEQ ID NO: 5, classified in class 800, subclass 3.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions in Groups 1-4, 7, 8, 17, 18, 21, and 22 are disclosed as biologically and chemically distinct, unrelated in structure and/or function, and/or made by and/or used in different methods and therefore, the claimed products are distinct.

Inventions in Groups 5, 6, 9-16, 19, 20, 23, and 24 are disclosed as materially different methods that differ at least in objectives, method steps, reagents and/or doses and/or schedules used, response variables, assays for end products and/or results, and criteria for success and therefore, the claimed methods are distinct.

Inventions 1/2 and 15,19/16,20 are related as product and process of use, respectively. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product, such as producing a transgenic animal.

Inventions 7/8 and 9,11,15/10,12,16 are related as product and process of use, respectively. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant

case the product as claimed can be used in a materially different process of using that product, such affinity chromatography.

Inventions 3/4 and 13/14 are related as product and process of use, respectively. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product, such affinity chromatography.

Inventions 21/22 and 23/24 are related as product and process of use, respectively. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product, such as determining whether expression of the heterologous protein in the transgenic animal affects the phenotype of said animal.

The inventions in groups 1-4/7/8/17/18/21/22 and 5/6 are not at all related because the products of groups 1-4/7/8/17/18/21/22 are not specifically used in any of the steps of the claimed methods in groups 5/6.

The inventions in groups 1-4/17/18/21/22 and 9-12 are not at all related because the products of groups 1-4/17/18/21/22 are not specifically used in any of the steps of the claimed methods in groups 9-12.

The inventions in groups 1/2/7/8/17/18/21/22 and 13/14 are not at all related because the products of groups 1/2/7/8/17/18/21/22 are not specifically used in any of the steps of the claimed methods in groups 15/16.

The inventions in groups 3/4/17/18/21/22 and 13/14 are not at all related because the products of groups 3/4/17/18/21/22 are not specifically used in any of the steps of the claimed methods in groups 15/16.

The inventions in groups 3/4/7/8/17/18/21/22 and 19/20 are not at all related because the products of groups 3/4/7/8/17/18/21/22 are not specifically used in any of the steps of the claimed methods in groups 19/20.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (703) 305-3008. The examiner can normally be reached on Monday-Thursday, alternate Fridays, 8:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Stephen L. Rawlings, Ph.D.
Art Unit 1642

slr
April 26, 2001

DONNA WORTMAN
PRIMARY EXAMINER